



CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

WARNING LETTER
2001-DT-15

May 9, 2001

Mr. Charles Heinbold Jr.
Chairman/CEO
Bristol-Myers Squibb Company
345 Park Ave.
New York, NY 10154

Dear Mr. Heinbold Jr:

On September 13, 2000, the Food and Drug Administration collected a sample of Casec Powder Protein Supplement Lot BAC11(#83646) from your firm to determine nutrient analysis of this product as a follow-up to a previous sample of Casec Powder Protein Supplement Lot BMN08 (#28827). The Office of Nutritional Products, Labeling and Dietary Supplements reviewed the labels and analytical worksheets for both samples of Casec Powder Protein Supplement which were manufactured by [REDACTED]. Both samples were determined to contain less sodium and fat than declared on the label.

Your product, CASEC Powder Protein Supplement, is misbranded within the meaning of section 403(a)(1) of the Federal Food, Drug and Cosmetic Act. We analyzed this product and found that it contained only 4% of the amount of sodium (100 mg) declared on the label. The product is misbranded in that the nutrition information does not accurately represent the sodium content in the food. It is your responsibility to ensure that all information on the product label is truthful and not misleading.

Please notify this office in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct this violation, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed. Also include copies of any available documentation demonstrating that corrections have been made.

Your written reply should be directed to Ms. Greta L. Budweg, Compliance Officer, U.S. Food and Drug Administration, 1560 E. Jefferson Ave., Detroit, MI 48207.

Sincerely yours,



David M. Kaszubski
Acting District Director
Detroit District

CC: 





